Diabetes Fear of Injecting and Self-Testing Questionnaire

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Diabetes Fear of Injecting and Self-Testing Questionnaire

A pschometric evaluation

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OBJECTIVE — To study the psychometric properties of the Diabetes Fear of Injecting and Self-Testing Questionnaire (D-FISQ).

RESEARCH DESIGN AND METHODS — Two groups of patients were studied. Sample A consisted of 252 insulin-treated diabetes patients. Sample B incorporated 24 insulin-treated patients with high scores (≥95th percentile) on the D-FISQ. Test-retest correlations were assessed in both samples. Discriminant and convergent validity of the D-FISQ were assessed with questionnaires concerning fear of hypoglycemia, trait anxiety, and fear of bodily injury, illness, or death. To evaluate criterion-related validity, sample B participated in a behavioral avoidance test (BAT), in which the current level of avoidance of either self-injecting or self-testing was determined. Exploratory factor analysis (EFA) was performed to study whether 2 factors (fear of self-injecting [FSI] and fear of self-testing [FST]) could be detected.

RESULTS — Test-retest correlations ranged from 0.50 to 0.68 ($P < 0.001$). Correlations between D-FISQ and fear of hypoglycemia, trait anxiety, and fear of bodily injury, illness, or death ranged from 0.28 to 0.45 ($P < 0.001$). Patients who refused to do a BAT for self-injecting or self-testing had higher scores on FSI ($P = 0.095$) and FST ($P = 0.01$). EFA yielded 2 separate factors, FSI and FST.

CONCLUSIONS — Results from this study support reliability and validity of the D-FISQ, a self-report instrument that can be used for both clinical and research purposes.

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Daily self-injecting of insulin and frequent self-monitoring of blood glucose (SMBG) are essential to adequately manage insulin-requiring diabetes. Extreme fear of self-injecting (FSI) insulin (injection phobia) is likely to compromise glycemic control as well as emotional well-being. Likewise, fear of SMBG (finger prick) can be a source of distress and may seriously hamper self-management. There is evidence to suggest that fear of blood and injury is associated with less frequent self-testing (1,2) and poor glycemic control (2). However, research concerning the etiology, prevalence, and treatment of FSI and fear of self-testing (FST) in patients with diabetes is scarce. To date, only a few studies, mostly case reports, have been published on the subject of FSI (3–8), and no research is known to us on FST.

To quantify the level of FSI as well as FST in adults with insulin-requiring diabetes, we developed a diabetes-specific questionnaire, the Diabetes Fear of Injecting and Self-Testing Questionnaire (D-FISQ), which consists of 2 subscales, FSI and FST (9,10). Subscale scores and a total score are obtained. Preliminary results suggested satisfactory psychometric properties. In the present study, stability of the D-FISQ was assessed over different periods of time, and construct, discriminant, and convergent validity were examined. Criterion-related validity was tested by means of a behavioral avoidance test (BAT), in which the actual self-injecting and self-testing behaviors of extreme scorers on the D-FISQ were examined. Moreover, we investigated the latent factor analytic structure of the D-FISQ.

RESEARCH DESIGN AND METHODS

Study subjects and procedure

Reliability: internal consistency and test-retest reliability. A composite questionnaire including the D-FISQ was sent to a random sample of 3,000 patients (with type 1 or 2 diabetes) drawn from ~40,000 members of the Dutch Diabetes Association (DVN, Diabetesvereniging Nederland). Inclusion criteria were *1*) age >16 years and *2*) being on insulin therapy for a minimum of 6 months. The latter criterion was chosen because we were interested in FSI/FST that persists beyond the early adaptation period. In total, 1,484 questionnaires were returned (49.5%); 12 questionnaires were excluded from data analyses because they were not complete. After exclusion of subjects not using insulin ($n = 197$), 1,275 subjects remained, from which a group of 252 subjects (sample A) was randomly selected. In this sample, internal consistency was assessed, as well as several aspects of validity. A second set of questionnaires, once more including the D-FISQ, was sent to this sample after ~3 months to determine test-retest reliability of the D-FISQ.

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Abbreviations: BAT, behavioral avoidance test; D-FISQ, Diabetes Fear of Injecting and Self-Testing Questionnaire; EFA, exploratory factor analysis; FSI, fear of self-injecting; FSS-III-R, Fear Survey Schedule III-R; FST, fear of self-testing; HFS-Worry, fear of hypoglycemia; IQR, interquartile Range; SMBG, self-monitoring of blood glucose; VAS, visual analog scale.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

From the 1,275 subjects, patients who scored in the ≥95th percentile on the FSI and/or FST subscale were approached for further research (n = 118; 36 patients scored in the ≥95th percentile on both FSI and FST). They were sent another composite questionnaire on which they indicated whether they would be willing to take part in an interview. A total of 79 patients (66.9%) returned this questionnaire, 50 of whom said they were willing to be interviewed (no statistically significant differences were found on sociodemographic variables between volunteers [n = 50] and refusers [n = 29] for the interview). Selective sampling was applied. Our aim was to have a balance in sex distribution in this sample and to create diversity in FSI and FST scores. Patients were contacted by telephone and given further information on the interview procedure, which included a BAT. If the patient agreed to cooperate, an appointment was made for the interview at the university. To assess the current level of FSI and FST, the patients filled out the D-FISQ before the interview. Patients who participated in the interview form sample B.

Validity. To assess construct validity, score distribution as well as intercorrelations of the D-FISQ and FSI and FST were considered in sample A. Discriminant and convergent validity were assessed by determining correlations between the D-FISQ and questionnaires concerning trait anxiety and fear of hypoglycemia (HFS-Worry). Furthermore, the association between the D-FISQ and fear of bodily injury, illness, or death, a subscale of the Fear Survey Schedule III-R, was determined. We expected moderate intercorrelations between the questionnaires, which would confirm an underlying susceptibility for anxiety/fear in patients.

Criterion-related validity of the D-FISQ was assessed by a BAT in sample B. This is a common procedure in behavioral sciences to determine a subject's level of avoidance of a feared object or situation. A gradual stepwise approach is formulated—from not being in contact with the phobic stimulus at all, to touching or handling it (11,12). A patient acquires a BAT score according to the number of steps that he or she is able to complete. In our case, the maximum score would be obtained when a patient was actually able to complete an insulin injection or finger prick. Refusing to do the BAT would be scored as a 0 (extreme avoidance). At the end of the interview (if it was not already clear), patients were asked which they feared most, injecting or self-testing, and whether they would be willing to perform that task. Patients were, therefore, only required to perform 1 BAT, namely for their primary fear. Injections were performed with an injection pen (NovoLet 1.5 ml or NovoPen 3; Novo Nordisk Farma, Alphen aan den Rijn, the Netherlands) the most common insulin pens in the Netherlands) with a saline solution provided by E.D.M. Patients were asked to bring along their own blood glucose monitoring equipment; otherwise, one of the authors (E.D.M.) provided them with a blood glucose meter (Acutrend Sensor Glucose; Boehringer Mannheim, Almere, the Netherlands). The BATs were videotaped and time-recorded. Patients were also asked to fill in a tension rating by means of a visual analog scale (VAS) (ratings ranged from 0 to 10: 0, not tense at all; 10, extremely tense) before and after the BAT to indicate how tense they felt. When the first BATs were performed, it became clear that patients either performed the task and completed it or refused altogether. Therefore, BAT scores were dichotomous: refused or completed. D-FISQ scores obtained before the interview were linked to the outcome of the BAT.

Factor analysis

An exploratory factor analysis (EFA) was performed to evaluate the presence of the 2 factors, i.e., FSI and FST.

Instruments

Questionnaires used in the first booklet were the D-FISQ (9,10) and the Dutch versions of the Problem Areas in Diabetes (13), the Worry-Scale of the Hypoglycemia Fear Survey (14,15), the trait scale of the State Trait Anxiety Inventory (16,17), the 12-item Well-Being Questionnaire (18,19), the Diabetes Coping Measure (20), the Hospital Anxiety and Depression Scale (21), and the Diabetes Quality of Life Measure (22).

The D-FISQ was developed by the authors and consists of 2 separate 15-item subscales, i.e., the FSI subscale and the FST subscale. First findings indicated high internal consistency, with Cronbach's α ranging from 0.90 to 0.94. High scores in FSI and FST coincided in ~40% of the cases (9). In the present validation study, we took the opportunity to add 4 items to both subscales of the D-FISQ to ensure that all relevant aspects of blood phobia were included. These items concerned dizziness, fainting, difficulty in concentrating, or becoming nauseous when self-injecting or self-testing, resulting in 2 subscales of 19 items. Items were presented as statements and were scored on a 4-point Likert scale, from 0 (almost never) to 3 (almost always). Subscale scores were calculated by summation (minimum score = 0, maximum score = 57). A total score could also be derived.

The Dutch version of the Worry-scale of the Hypoglycemic Fear Survey (14,15) was used, a diabetes-specific instrument that detects the level of fear with respect to hypoglycemic reactions (Cronbach's α = 0.92). The Dutch adaptation of the State-Trait Anxiety Inventory trait subscale (16,17) was used to assess anxiety as a trait (Cronbach's α = 0.87–0.92).

The second booklet of questionnaires, which was sent to people who scored in the ≥95th percentile on FSI and/or FST, included the following measures: the Netherlands Personality Questionnaire (23) and the Dutch versions of the Fear Survey Schedule III-R (FSS-III-R) (24), the Becks Depression Inventory (25), and the Symptom Checklist 90 (26). FSS-III-R distinguishes 5 types of fears/phobias. One of its subscales addresses fear of bodily injury, illness, or death (12 items, Cronbach's α = 0.77–0.84) and includes items on fear of needles and blood.

The study protocol was approved by the Ethics Committee of the University Hospital of the Vrije Universiteit Amsterdam, and written informed consent was obtained from the patients (sample B) for the interview and the BAT procedure.

Statistical analyses

Statistical analyses were performed using SPSS 7.5 for Windows (SPSS, Chicago) (27). Values are expressed as means ± SD for normally distributed data or as median with range and interquartile range for skewed data. Spearman's rank correlation coefficients were calculated to determine associations between various variables, as well as test-retest reliability. Analyses included unpaired Student's t tests and χ^2 tests. Cronbach's α was determined for internal consistency. Corrected item-total correlations were obtained. $P < 0.05$ was considered to be statistically significant, and $P < 0.10$ was regarded as a trend. As a prerequisite to EFA in sample A, all items of the 2 subscales were screened for their contribution to the D-FISQ. Items with low variance (<5% of scores >0) were excluded; exceptions were made for items that were considered to be highly clinically relevant. In EFA, items loading ≥|0.40| were accepted (28). In our earlier research, self-injecting

and self-testing were found to be significantly correlated (9), therefore oblique rotation (direct oblimin) was considered appropriate (28). Mann-Whitney *U* tests were performed to examine group differences in D-FISQ scores.

Internal consistency was determined of the factors found in EFA. Moreover, κ-coefficients were used to determine the measure of agreement between the D-FISQ and the factors found in EFA.

RESULTS — Characteristics of samples A and B are shown in Table 1. Of the 50 subjects who could be approached for an interview in view of their D-FISQ score and were willing to cooperate, 24 patients were selected and agreed to participate (sample B). The remaining 26 nonparticipants in the interview had a significantly longer duration of insulin use ($P < 0.05$), but otherwise no significant differences were found on sociodemographic variables between participants and nonparticipants in the interview.

No significant differences were found on sociodemographic characteristics between samples A and B, although a trend exists ($P < 0.10$) toward more female patients, shorter durations of insulin use, and lower numbers of self-reported self-tests in the fearful group. Response to the 3-month retest was 90.5% ($n = 228$, 49.1% men, mean age 48.5 ± 15.4 years, 58.3% with type 1 diabetes).

Table 1—*Sample characteristics*

Variable	Sample A	Sample B
n	252	24
Men (%)	49.2	29.2
Age (years)	47.9 ± 15.4	44.5 ± 16.7
Type 1 diabetes (%)	60.7*	45.8*
Diabetes duration (years)		
0–5 (%)	19.4	29.2
6–10 (%)	18.3	20.8
11–20 (%)	34.1	33.3
≥21 (%)	27.0	16.7
Years of insulin use (%)		
0–5	28.2	54.2
6–10	18.3	8.3
11–20	25.4	25.0
≥21	21.0	12.5
HbA_{1c} (self-reported)	7.8 ± 1.7†	7.8 ± 1.9†
Self-injection rate per day (%)		
1–2	31.7	41.7‡
≥3	67.5	54.3
Self-testing rate per week (%)		
0–5	45.6	70.8
6–10	16.7	16.7
11–20	17.9	0.0
≥21	17.5	12.5

Data are *n*, means ± SD, or %. Percentages do not add up because of missing values. All patients were insulin-treated. *Patients <40 years of age at the time of diagnosis and who were treated with insulin from diagnosis were regarded as type 1 diabetic patients. Patients who did not meet these criteria were considered type 2 diabetic patients. †Only 64.3% of sample A and 50.0% of sample B reported their HbA_{1c} levels. ‡One patient used an insulin pump.

Reliability: internal consistency and stability

Internal consistency (Cronbach's α) for the respective subscales, as calculated in sample A, were 0.89 (FSI) and 0.97 (FST).

No statistically significant difference in mean scores was found between test and retest on FSI or FST (data not shown). Spearman's correlation between test and retest was 0.58 ($P < 0.001$) for FSI and 0.50 ($P < 0.001$) for FST after a 3-month interval. Because of skewed score distributions, Spearman's ρ was also determined for the group that scored >0 on both test and retest; correlations were 0.66 ($n = 30$, $P < 0.01$) for FSI and 0.51 ($n = 36$, $P < 0.01$) for FST.

Test-retest reliability was also determined in sample B ($n = 24$), with a mean time interval of 15 months (range 11–20). Spearman's correlation between the 2 measurements was 0.68 ($P < 0.001$) for FSI and 0.50 ($P < 0.01$) for FST. In both samples A and B, there was no significant relationship (Spearman ρ) between duration of diabetes/insulin use and the difference in scores over time (data not shown).

Validity

Construct validity. As expected, FSI and FST scores in sample A showed a highly skewed distribution. A total of 191 subjects (75.8%) obtained a score of 0, which is the lowest possible score, on FSI (interquartile range [IQR]: 0,0); 176 patients (69.8%) scored 0 on FST (IQR: 0,1). No statistically significant differences were found between men and women on FSI/FST scores. Spearman's correlations between the D-FISQ and its subscales were 0.79 (FSI-D-FISQ), 0.91 (FST-D-FISQ), and 0.56 (FSI-FST) ($P < 0.01$).

Discriminant and convergent validity. Spearman's correlations between the D-FISQ and its subscales and trait anxiety ranged from 0.31 to 0.45 ($P < 0.001$). Spearman ρ's with HFS-Worry were 0.30–0.36 ($P < 0.001$). Correlations between D-FISQ scales and the FSS-bodily injury, illness, or death subscale varied from 0.28 to 0.32 ($P < 0.001$).

Criterion-related validity. FSI scores of the patients who participated in the BAT ($n = 24$) on the self-injecting subscale ranged from 0 to 26; scores on the self-testing subscale (FST) ranged from 2 to 44.

Fear of self-injecting

A total of 7 subjects of the 24 interviewees indicated that they experienced most problems with self-injecting. They were therefore asked if they would perform a self-injection in the BAT with an insulin pen containing a saline solution. The FSI scores (at the time of the interview) of these 7 patients ranged from 0 to 26. The 2 highest-scoring patients (scores of 25 and 26) stated they were unable to perform the behavioral test because of anxiety. Both patients showed a marked increase in FSI score (>10 points) since the previous completion of the D-FISQ of ~1 year earlier. Furthermore, these 2 patients had higher scores on FSI than patients who completed the BAT (Mann-Whitney *U* test, $Z = -1.94$, $P = 0.095$).

The other 5 patients were able to complete the BAT. Their FSI scores ranged from

Table 2—*Forced 2-factor solution after exploratory factor analysis of 17 items of the D-FISQ*

Item content	Factor 1 FSI	Factor 2 FST	Communality
When I have to inject myself:			
I become restless	0.75		0.58
I feel tense	0.83		0.74
I feel afraid	0.65		0.38
I worry about it	0.67		0.46
I feel nervous	0.72		0.63
I brood about it	0.50	0.40	0.52
I try to postpone it		0.56	0.38
I get angry		0.48	0.38
When I have to prick my finger:			
I become restless		0.70	0.57
I try to avoid it		0.72	0.49
I feel tense		0.62	0.52
I feel afraid		0.77	0.64
I worry about it		0.73	0.57
I feel nervous		0.65	0.61
I brood about it		0.74	0.59
I try to postpone it		0.76	0.53
I get angry		0.73	0.51
Eigenvalue before rotation	6.7	2.3	
Eigenvalue after rotation	6.0	4.2	
% Variance before rotation	39.5	14.0	

Oblimin rotation was used. Loadings $<|0.40|$ are not shown.

0 to 13; 3 patients' scores had dropped slightly (1–3) compared with the previous D-FISQ scores, and 1 patient reported that he did not experience fear anymore (score dropped from 11 to 0). Tension ratings ranged from 0.4 to 5.8 (mean 3.3). Mean time needed to complete the injection was 22 s (range 12–33).

Fear of self-testing

Of the 24 patients participating in the interview, 17 patients indicated that they were most anxious about self-testing. They were therefore requested to perform a self-test in the BAT. The FST scores of these 17 patients ranged from 2 to 44. A total of 4 patients were not able to perform a self-test in the BAT, with FST scores in the range of 20–44. Since the previous D-FISQ completion, in 3 of the cases their scores had increased (2–20 points), and 1 patient's score dropped from 25–20. These 4 patients who declined to do the BAT scored significantly higher on FST than patients who did complete the test (Mann-Whitney *U* test, $Z = -2.49$, $P = 0.01$). The remaining 13 patients were all able to complete the BAT (mean tension rating 3.7). Of the remaining patients, 3 had relatively high scores of >20 (range 21–29, 6–18 points higher than the first D-FISQ measurement), 2 of whom reported tension ratings of 9.3 and 6.5. The third patient reported a tension rating of only 3.5; however, she needed nearly a minute (57 s) to perform a self-test (mean time needed for SMBG = 19 ± 15 s, not including waiting time for reading the result).

The FST scores of the other 10 subjects ranged from 2 to 15; 7 scores had decreased since the last D-FISQ (2–11 points), 2 scores had increased (1 and 4 points). Tension ratings were 0.3–7.2.

Factor analysis

Before EFA, items with low variance (<5% of scores >0) were excluded, among which were also the 4 items that had been added to both original subscales. The 2 items "I feel afraid when I have to inject myself/when I have to prick my finger" did not meet the 5% criterion but were not excluded for clinical reasons. In total, 17 items remained for EFA (Table 2). Two forced factors were calculated in EFA, resulting in 2 factors of, respectively, 6 and 11 items, which accounted for 39.5 and 14.0%, respectively, explained variance before rotation (Table 2). The 2 factors were evaluated for internal consistency. Corrected item-total correlations ranged from 0.55 to 0.72 in factor 1 and from 0.48 to 0.73 in factor 2, and Spearman ρ correlation between the 2 factors was 0.57 ($P < 0.01$). Cronbach's α of factor 1 (0.81) and factor 2 (0.88) were satisfactory. The measure of agreement for dichotomized scores (at 95% level) was determined between D-FISQ subscales and the respective factors derived from EFA. κ Coefficients between these dichotomized scores were 0.84 (FSI [factor 1]) and 0.83 (FST [factor 2]), respectively, (both $P < 0.001$). Using a 95% cutoff point on these factor scores, the EFA factors identified all patients in the total population who scored on or above the scores of the BAT refusers on FSI or FST.

CONCLUSIONS — Results from this study substantiate earlier research in supporting the psychometric properties of the D-FISQ. Homogeneity of the D-FISQ may be considered high, and test-retest reliability for FSI was satisfactory. We found moderate test-retest correlations for FST, suggesting that FST is less stable over time than FSI. To further explore the fluctuations in FST, a test-retest procedure for FST over a shorter period of time (i.e., 1–2 weeks) may prove useful. Validity of the D-FISQ was supported by the distribution of D-FISQ scores and the moderate correlations with fear of hypoglycemia and trait anxiety, corroborating our earlier findings (9); these moderate intercorrelations may be demonstrating a common fear susceptibility underpinning the specific constructs of the questionnaires. The modest association found between D-FISQ scores and the generic phobia questionnaire FSS-III-R substantiates the need for a diabetes-specific instrument. What is more, results from the EFA bear out the existence of separate scales—FSI and FST—2 specific fears that appear to be intercorrelated but are clearly 2 different constructs.

Data from the BAT support criterion-related validity of the D-FISQ. For the BAT, we relied on observation of behavior and self-reported anxiety. Although physiological arousal as a consequence of anxiety during the BAT can be determined (e.g., heart rate, galvanic skin response, blood pressure), we decided not to use these methods, because parasympathetic reactions can be affected by diabetes and results would therefore be difficult to interpret.

Patients who refused the BAT had higher FSI/FST scores than patients who managed to complete the BAT. The differ-

ence in scores between those who refused and those who completed the BAT was significant for FST but did not reach significance for FSI, which may be because of the small number of subjects.

It should be noted that being able to perform the BAT does not discern whether a patient actually adheres to his or her regimen in daily life. No difference was found in HbA_{1c} between samples A and B, but these data concern self-reported HbA_{1c} values, with a large number of missing data. However, a trend was found toward patients from sample B (extreme scorers) performing fewer self-tests than sample A. More research is warranted to address both the psychological and glycemic consequences of FSI and FST in patients with diabetes.

We consider the FSI and FST subscale scores to be of high clinical and research value, but it seems less useful to calculate a total score, given the fact that high scores on FSI and FST overlap in only 40% of the cases (9).

Results from the EFA suggest that the D-FISQ can be shortened, with Cronbach's α's for both subscales somewhat lower, but still highly satisfactory (29). Also, there is a satisfactory level of agreement between the D-FISQ and the EFA factors. Moreover, none of the patients scoring at the level of BAT refusers would be missed when using a 95% cutoff point in the shortened version. Further research into the clinical usefulness of the potential short version of the D-FISQ is warranted.

In conclusion, the results of the present study support validity and reliability of the D-FISQ, a brief, easy-to-administer self-report questionnaire that may prove useful for both researchers and clinicians working with insulin-treated diabetes patients.

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